



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

6/2/2017

John Fournier
Agent for Earth Science Laboratories
c/o Acadia Regulatory Consulting
331 W. King Road
Ithaca, NY 14850

RE: Application for Registration dated 8/22/2016
Product Name: Earthtec II
EPA File Symbol: 64962-T
Decision Number: 526501

Dear Mr. Fournier:

Our records indicate that the decision review period for EPA to make a determination pursuant to section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA), as amended, regarding the above referenced application ends on 6/5/2017. The Agency has reviewed the application. On 5/16/2017, the Agency informed you that the application was inadequate and described the deficiencies to be addressed. The Agency communicated on several occasions what must be done to resolve the issues with this application. The initial explanation of the issues and necessary revisions to the application was made in a phone call 3/7/2017. An email reminder was sent 3/30/2017, followed by another on 4/21/2017. The registrant committed in an email dated 4/25/2017 to submit the necessary documents on 4/25/2017, but they were never received. The last follow-up call by the Agency was made 5/12/2017. The registrant stated intent to send revised documents later that day in our last call. When nothing had been received by 5/16/2017, the Agency sent a 75-day letter, in which it was indicated that a response from the registrant resolving issues with the application was necessary by 5/18/2017 in order for EPA to meet the PRIA due date of 6/5/2017. Receipt of the 75-day letter was confirmed by the registrant 5/16/2017; however, no response beyond confirmation of receipt was submitted.

The Agency, in meeting its obligation to make a determination within the PRIA decision review period, has determined that your application does not meet the standard for registration under FIFRA and, therefore, cannot be granted at this time.

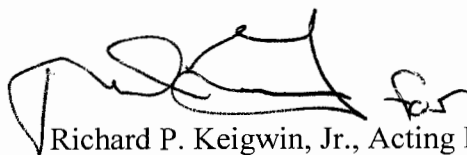
The application's deficiencies were identified in the attached 75-day notice.

Although this concludes EPA's PRIA review of your application, this determination is not a denial of your application pursuant to section 3(c)(6) of FIFRA. You have the following four options.

1. **Resolve the issue(s).** You may resolve the issue(s) identified in the Agency letter dated 5/16/2017 by submitting the information/data/studies by 7/30/2017 or an explanation of why it will take longer to correct the deficiency or deficiencies, including your written commitment and schedule to respond to the deficiencies. The Agency will then continue to diligently work with you in resolving the deficiencies without a PRIA decision due date.
2. **Do nothing.** If you do not respond to this letter, the Agency will administratively withdraw your application on 7/30/2017. Once the application is withdrawn, if you decide to pursue this action again, you will need to submit a new application, including either the appropriate fee or 25% or 50% of the fee and a request for a waiver of the remainder of the fee.
3. **Withdraw the application.** You may withdraw your application. Once the application is withdrawn, if you decide to pursue this action again, you will need to submit a new application, including either the appropriate fee or 25% or 50% of the fee and a request for a waiver of the remainder of the fee.
4. **Request a denial.** Because this determination is not a denial under section 3(c)(6) of FIFRA, you may request that EPA issue such a denial by responding to the Agency prior to 7/30/2017. The Agency may then initiate a denial process, based upon the record before the Agency as of the date of this letter, as described in section 3(c)(6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

If you have questions concerning or a response to this letter, please contact Lindsay Roe at 703-347-0506 or by email at roe.lindsay@epa.gov or Tony Kish at 703-308-9443 or by email at kish.tony@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Keigwin, Jr.', with a stylized flourish at the end.

Richard P. Keigwin, Jr., Acting Director
Office of Pesticide Programs
US Environmental Protection Agency

Enclosure: "Data Deficiency"- 75 day letter dated 5/16/2017



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5/16/2017

John Fournier
Agent for Earth Science Laboratories
c/o Acadia Regulatory Consulting
331 W. King Road
Ithaca, NY 14850

Subject: Data Deficiency
Product Name: Earthtech II
EPA Registration Number: 64962-T
Application Date: 8/22/2016
Decision Number: 526501

Dear Mr. Fournier:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described in a telephone call 3/7/2017, followed by an email 3/30/2017, an email 4/21/2017, and a phone call 5/12/2017, pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending 7/30/2017 to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The CSF for this product is set up as a 100% repack; however, that is not acceptable for a product using the same formulation as another of its own products.
2. Data compensation for this product is covered using formulator's exemption; however, formulator's exemption does not apply between products with the same registrant.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

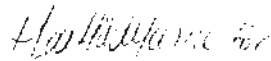
FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on 6/5/2017. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75-day letter. If you choose this option, you need to contact the Agency not later than 5/18/2017 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than 5/18/2017 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by 5/18/2017, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by 5/18/2017 by contacting Lindsay Roe at 703-347-0506 or by email at roe.lindsay@epa.gov during the hours of 7:00 am to 5:30 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script, appearing to read "Tony Kish".

Tony Kish, Product Manager 22
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs